



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,745	02/28/2002	Gary de Jong	24601-416C	8781
20985	7590	07/02/2004		
FISH & RICHARDSON, PC 12390 EL CAMINO REAL SAN DIEGO, CA 92130-2081			EXAMINER LAMBERTSON, DAVID A	
			ART UNIT	PAPER NUMBER
			1636	
DATE MAILED: 07/02/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,745

Applicant(s)

DE JONG ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-22,31,33 and 35-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18-22 is/are allowed.
- 6) ☒ Claim(s) 17,31 and 33 is/are rejected.
- 7) ☒ Claim(s) 35-39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Receipt is acknowledged of a reply to the previous Office Action, filed April 14, 2004. Amendments were made to the claims. Specifically, claim 34 was cancelled and new claims 35-41 were added.

Claims 1-22, 31, 33 and 35-41 are pending and under consideration in the instant application. Any rejection of record in the previous Office Action, mailed January 28, 2004, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

Information Disclosure Statement

The information disclosure statements filed March 3, March 26 and April 22, 2004 have been considered, and a signed and initialed copy of the form PTO-1449s have been attached to this Office Action. It is noted that the IDS filed March 3, 2004 is a duplication of the IDS filed October 30, 2002, with corrections made to references AS-BC. References AS-BC have been considered on the record, but the remaining references are crossed through as being substantial duplicates of the references already considered in the October 30, 2002 IDS.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

Art Unit: 1636

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17, 31 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Nolan *et al.* (WO 00/34436; see entire document; henceforth Nolan). **This is a new rejection necessitated by amendment.**

Nolan teaches a method and apparatus that employs fluorescence activated cell sorting (FACS) to verify the delivery of at least one chromosome into a host cell of interest (see for example page 5, lines 10-20). Nolan defines a chromosome as on the order of 1-10 mega bases (see for example page 8, lines 21-22), thereby meeting the new limitation of “large nucleic acid” as defined by the instant specification. The method taught by Nolan indicates that it is preferred that the chromosome be fluorescently labeled, and then detected using high speed fluorimetry (see for example pages 9-10, the bridging paragraph). Nolan further indicates that a host cell of interest includes fibroblasts and parenchyma stem cells (see for example page 8, lines 28-29), thereby meeting the limitations of dependent claim 31. It is also clear from the teachings of Nolan that the number of cells are determined following FACS analysis, as when the cells are sorted a histogram is displayed indicating the quantity of cells possessing the fluorescent property being detected (see for example page 1-2, the bridging paragraph, especially lines 5-7 on page 2).

Response to Arguments Concerning Claim Rejections - 35 USC § 102

Applicant's arguments with respect to claims 17, 31 and 33 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1636

It is noted that Applicant has amended the claims to contain a new limitation whereby the nucleic acid must be "large" (i.e., greater than 0.5 MB in size). Applicant argues that this limitation is not present in the references applied in the previous Office Action. However, this new limitation is present in the reference applied in the new rejection, which was necessitated by the amendment to the claims. Therefore, Applicant's arguments are moot in view of the new rejection, which meets the newly added limitation.

Allowable Subject Matter

Claims 35-39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 18-22, 40 and 41 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

Art Unit: 1636


however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David A. Lambertson, Ph.D.
AU 1636



**JAMES KETTER
PRIMARY EXAMINER**